

## REMARKS

Applicant submits this Amendment After Final in reply to the final Office Action mailed December 6, 2005.

By this Amendment After Final, Applicant cancels claims 11 and 30, without prejudice or disclaimer, amends claims 1, 24, 25, and 35, and adds new claims 37-60. The originally-filed specification, drawings, and claims fully support the subject matter of amended claims 1, 24, 25, and 35, and new claims 37-60. In particular, independent claims 1 and 24 have been rewritten to include the subject matter of dependent claims 11 and 30. No new matter has been introduced.

Before entry of this Amendment After Final, claims 1-36 were pending in this application. After entry of this Amendment After Final, claims 1-10, 12-29, and 31-60 are now pending in this applications. Claims 1, 16, 24, 43, and 52 are the sole independent claims.

On pages 2-3 of the final Office Action, claims 1-36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,359,993 to Slater et al. ("Slater") in view of U.S. Patent No. 5,518,927 to Malchesky et al. ("Malchesky"). Applicant respectfully traverses this rejection. No combination of Slater nor Malchesky discloses or suggests each and every aspect of the pending claims as required for a *prima facie* case of obviousness.

For example, independent claim 1 recites, among other aspects, "wherein the indicator is configured to be substantially the same color as a portion of the medical device before being exposed to the particular environment." Independent claims 16 and 24 recite similar aspects. In rejecting the subject matter of now-cancelled dependent

claims 11 and 30, page 3 of the final Office Action asserts that col. 6, lines 43-50 of Malchesky discloses that “the indicator of Malchesky is configured to be substantially the same color as a portion of the medical device before being exposed to the particular environment.” Applicant respectfully disagrees. The cited portion of Malchesky discloses an indicator material having two portions. A first portion has a predetermined shape impregnated with the color change indicator. A second portion surrounds the predetermined shape and has a similar pigment but is insensitive to oxidants. Thus, when exposed to oxidants, the predetermined shape will change color while the rest of the material will not, allowing the predetermined shape to become visible. In this portion of the specification, Malchesky does not disclose a color of the underlying medical device. Instead, Malchesky only discloses a relationship between a portion of the color change material and the rest of the material, and does not disclose any relationship between the color of the color change indicator and the instrument as set forth in independent claims 1, 16, and 24.

New independent claim 43 recites, among other aspects, “wherein the chemical is configured to change to a first color when exposed to a first environment and change to a second color different from the first color when exposed to a second environment different from the first environment.” No combination of Slater and Malchesky discloses or suggests this aspect either alone or in combination with the other respective aspects of the independent claim.

New independent claim 52 recites, among other aspects, a medical device including a plurality of color changing indicators. In rejecting claims 14, 22, and 32, page 4 of the final Office Action asserts that col. 6, lines 30-36 of Malchesky discloses a

plurality of color changing indicators. Applicant respectfully disagrees. Fig. 6 and col. 6; lines 30-36 merely disclose a scale 30 (or more accurately a legend). Portions 32, 34, 36 of scale 30 are not color change materials, i.e., they do not change color. Instead scale 30 is a reference to be placed on the instrument to compare with the color change material and determine, based on the color of the color change material relative to portions 32, 34, 36, whether to reuse or discard the instrument. Accordingly, Malchesky does not disclose placing a plurality of color change indicators on instruments as set forth in independent claim 52.

Accordingly, for at least the aforementioned reasons, Applicant respectfully requests withdrawal of the Section 103(a) rejections based on Slater and Malchesky.

Claims 2-10, 12-15, 17-23, 25-29, 31-42, 44-51, and 53-60 depend from one of independent claims 1, 16, 24, 43, and 52, and are therefore allowable for at least the same reasons that each of the corresponding independent claims is allowable. In addition, each of the dependent claims recite unique combinations that are neither taught nor suggested by Slater and Malchesky, and therefore are separately patentable.

Applicant respectfully requests that this Amendment After Final under 37 C.F.R. § 1.116 be considered by the Examiner, placing claims 1-10, 12-29, and 31-60 in condition for allowance. Applicant submits that there are no new issues raised that necessitate the undertaking of any additional search of the art by the Examiner. Therefore, this Amendment After Final should allow for immediate action by the Examiner.

Furthermore, Applicant respectfully points out that the final Office Action presented some new arguments as to the application of the art against Applicant's

invention. It is respectfully submitted that the consideration of the Amendment After Final would allow the Applicant to reply to the final rejections and place the application in condition for allowance.

In view of the foregoing remarks, Applicant submits that this claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the reconsideration and reexamination of the application, and the timely allowance of the pending claims.

The final Office Action contains characterizations of the claims and the related art with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to these or any other statement or characterization in the final Office Action.

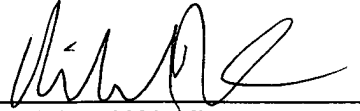
In discussing the specification and claims in this Amendment After Final, it is to be understood that Applicant is in no way intending to limit the scope of the claims to any exemplary embodiments described in the specification or abstract and/or shown in the drawings. Rather, Applicant is entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

Please enter any extension of time necessary to submit this Amendment After  
Final, and charge any required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: January 18, 2006

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